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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/661,413	09/13/2000	Zafiris G. Zafirelis	CAT-11	7935

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EXAMINER

LE, HUYEN D

ART UNIT

PAPER NUMBER

3751

DATE MAILED: 01/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/661,413

Applicant(s)

ZAFIRELIS ET AL.

Examiner

Huyen Le

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-51 is/are pending in the application.
- 4a) Of the above claim(s) 43,46 and 47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9,18-20,22,24,29-34,48 and 51 is/are rejected.
- 7) ☐ Claim(s) 10-17,21,23,25-28,41,42,44,45,49 and 50 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Regarding the restriction requirement, the current application contains two different inventions

I. Claims 1-42, 44, 45, 48-51 drawn to a system and method of assisting flow of blood by a patient heart, are classified in class 604, subclass 6.11.

II. Claims 43, 46 and 47 drawn to a sub-system such as a pump, classified in class 417, subclass 1.

2. Applicant's election with traverse of Invention I in Paper No. 6 is acknowledged. The traversal is on the ground(s) that the search of claim 1 (invention I) includes the scope of the invention II. This is not found persuasive because invention I and II are related as combination and subcombination. In the case, the invention I does not require the details of the particular controller of the invention II which carefully control and monitor the speed of pump, flow rate and pressure in the pump. The invention II has a separate utility as a pump for different uses other than pumping blood through a heart.

The requirement is still deemed proper and is therefore made FINAL.

Therefore, claims 43, 46 and 47 are withdrawn from consideration as being directed to the non-elected invention.

Drawings

3. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "inflow valve and a

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perfusion valve must be shown or the features canceled from the claim 21. No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 22 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claim 22 recites the limitation "the controller" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-6, 29-34, 48 and 51 are rejected under 35 U.S.C. 102(b) as being anticipated by Hirose et al (5,449,342).

The Hirose et al reference disclose a system for assisting flow of blood by a patient's heart comprising a transseptal cannula 1 adapted to be inserted in the femoral

vein and extend through the atrial septum from the right atrium to the left atrium, a blood pump mechanism (Fig. 7), and a perfusion cannula 8 adapted to be inserted in the femoral artery for returning oxygenated blood to the arterial system of the patient, the perfusion cannula connected to the blood pump outlet.

In regard to claim 2, the blood pump includes a transseptal clamp mechanism 5 for clamping the blood pump to the transseptal cannula 1.

In regard to claim 3, the blood pump is adapted to be within 3 feet of where the transseptal cannula and the output cannula are positioned to enter the patient (col. 4, line 4).

In regard to claim 4, the blood mechanism includes tubing 3, 8 which connects the blood pump to the transseptal cannula 1 and the perfusion cannula 8 and the clamp mechanism 5.

In regard to claims 29-34, the method for assisting blood flow by a patient's heart is inherently performed during the operation of the system.

9. Claims 1-6, 29-34, 48 and 51 are rejected under 35 U.S.C. 102(b) as being anticipated by Fonger et al (5,190,528).

The Fonger et al reference disclose a system for assisting flow of blood by a patient's heart comprising a transseptal cannula 3 adapted to be inserted in the femoral vein and extend through the atrial septum from the right atrium to the left atrium, a blood pump mechanism 37 (Fig. 7), and a perfusion cannula 41 adapted to be inserted in the femoral artery for returning oxygenated blood to the arterial system of the patient, the perfusion cannula 41 connected to the blood pump outlet 37.

In regard to claim 2, the blood pump includes a transseptal clamp mechanism 18 for clamping the blood pump to the transseptal cannula 3.

In regard to claim 3, the blood pump is adapted to be within 3 feet of where the transseptal cannula and the output cannula are positioned to enter the patient.

In regard to claim 4, the blood mechanism includes tubing 3 which connects the blood pump 37 to the transseptal cannula 3 and the perfusion cannula 41 and the clamp mechanism.

In regard to claims 29-34, the method for assisting blood flow by a patient's heart is inherently performed during the operation of the system.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hirose et al (5,449,342).

Although the Hirose et al reference is not specific about the blood pump having a rotor and stator, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a blood pump such as a centrifugal pump (see col. 5, lines 59-60) that would inherently include a rotor and stator.

12. Claims 8, 9, 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hirose et al (5,449,342) in view of Wampler (5,840,070).

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Although the Hirose et al reference does not disclose that the system for assisting flow of blood include a controller for operating the blood pump, such an electronic controller is known in the pump art. Attention is directed to the Wampler reference which discloses an electronic controller 59 for controlling a blood pump (see col. 8, lines 56-64)

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a controller for the Hirose et al pump in view of the teaching of Wampler for controlling and adjusting the speed of the pump.

In regard to claim 9, a centrifugal pump would inherently include an impeller.

13. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hirose et al (5,449,342).

Although the Hirose et al reference does not disclose a holding mechanism which holds and attaches the blood pump to the patient, such a feature is conventional. It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a holding mechanism for conveniently attaching the blood pump to a user.

14. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fonger et al (5,190,528).

Although the Hirose et al reference is not specific about the blood pump having a rotor and stator, it would have been obvious to one of ordinary skill in the art at the time that a blood pump such as a centrifugal pump (see col. 7, lines 45-46) would inherently include a rotor and stator.

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15. Claims 8, 9, 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fonger et al (5,190,528) in view of Aboul-Hosn (6,083,260).

Although the Fonger et al reference does not disclose that the system for assisting flow of blood include a controller for operating the blood pump, such an electronic controller is conventional in the pump art. Attention is directed to the Aboul-Hosn reference which discloses an electronic controller for controlling a blood pump (see col. 14, lines 36-39).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a controller for the Hirose et al pump in view of the teaching of Aboul-Hosn for controlling and adjusting the speed of the pump.

In regard to claim 9, a centrifugal pump would inherently include an impeller.

16. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fonger et al (5,190,528).

Although the Fonger et al reference does not disclose a holding mechanism which holds and attaches the blood pump to the patient, such a feature is conventional. It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a holding mechanism for conveniently attaching the blood pump to a user.

Allowable Subject Matter

17. Claims 10-17, 21, 23, 25-28, 41, 42, 44, 45, 49 and 50 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in

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independent form including all of the limitations of the base claim and any intervening claims.


Conclusion

18. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The Takano et al and Stevens et al references show systems for assisting flow of blood by a patient's heart. The Hinchliffe et al, Farrell, Roberts et al and Loubser reference show blood pump systems.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Huyen Le whose telephone number is 703-306-5504. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gregory Huson can be reached on 703-308-2580. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-7766 for regular communications and 703-308-7766 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0861.



DAVID J. WALCZAK
PRIMARY EXAMINER

HL
January 10, 2003